

REMARKS**I. Status of the Claims and Formal Matters**

Claims 1-7 and 9-27 are presently pending in this application. Claims 21 and 22 are withdrawn from consideration. Claims 1, 12 and 28 are amended. Claims 26 and 27 are cancelled.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendment of the claims, as presented herein, is not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, this amendment is made simply for clarification and to round out the scope of protection to which Applicants are entitled. Furthermore, it is explicitly stated that the herewith amendment should not give rise to any estoppel.

Reconsideration and withdrawal of the objections to and the rejections of this application in view of the amendments and remarks herewith, is respectfully requested, as the changes place the application in condition for allowance.

II. The Rejections Under 35 U.S.C. § 112 Are Overcome

Claims 1-7, 9-16, 23-26 and 28 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. It is alleged that the specification as originally filed fails to disclose applying electromagnetic energy at a wavelength of “at least about 488 nm” or creating a tissue seal having “the tensile strength of the tissue.” Applicants respectfully traverse this rejection.

The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976), M.P.E.P. 2163. The rejection must set forth express findings of fact which support the lack of written description conclusion. These findings should establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed.

It is respectfully submitted that the instant Office Action has provided no findings of fact to support the rejections and furthermore, has provided no rationale as to why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention. Nonetheless, amendments to the claims are presented in an attempt to expedite prosecution of the present application.

Independent claims 1, 12 and 28 have been amended to recite applying electromagnetic energy at a wavelength of at least 488 nm. In a preferred embodiment of the invention, the wavelength to be applied is between about 400 nm and about 700 nm. See, paragraph 57 of U.S. Patent Application Publication No. 2002/0022606, published on February 21, 2002. Use of a longer wavelength in the claimed methods results in better penetration, which in turn produces longitudinal bonding within a target tissue. Support for the use of wavelengths of at least 488 nm is found in Example 1 (paragraph 76 of U.S. Patent Application Publication No. 2002/0022606), where exemplary excitation wavelengths above 400 nm are described to be at least 488 nm:

“The photosensitizers, their absorption maxima, and their absorption coefficients at the laser wavelength used in this Example were, e.g., rose bengal (RB), 550 nm, 33000 dm³ mol⁻¹ cm⁻¹ at 514 nm; fluorescein (Fl), 490 nm, 88300 dm³

$\text{mol}^{-1} \text{cm}^{-1}$ at 488 nm; methylene blue (MB), 664 nm, $15600 \text{ dm}^3 \text{ mol}^{-1} \text{ cm}^{-1}$ at 661 nm; riboflavin-5-phosphate (R-5-P), 445 nm, $4330 \text{ dm}^3 \text{ mol}^{-1} \text{ cm}^{-1}$ at 488 nm;...” [emphasis added].

The applicants draw support from the description in the specification of this specific embodiment of the invention for the amendment to the claims presented herein. One skilled in the art of photodynamic medicine would readily understand this passage to describe a specific embodiment of the invention where suitable wavelengths above 400 nm are described to be at least 488 nm. The term “about” has been deleted to more clearly define the subject matter of the claims.

Independent claim 1, as amended, is directed to a method for tissue repair in which the repaired tissue has tensile strength. Support for this amendment can be found, for example, at paragraph 49 of U.S. Patent Application Publication No. 2002/0022606:

“Methods of the invention provide high tensile strength repair and have no requirement for an exogenous protein, e.g., fibrinogen, that must be isolated from the patient to be treated or derived from one or more donors.”

This description in the specification places the applicants in clear possession of the invention of claim 1.

Claims 26 and 27 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. It is alleged that the limitation “amniotic membrane therapy” is not enabled by the disclosure in the specification. Amniotic membrane therapy is described at paragraphs 25 and 36 of the specification. See, paragraphs 25 and 36 of US Patent Application Publication No. 2002/0022606.

Applicants respectfully traverse this rejection, however to expedite prosecution of the present application, claims 26 and 27 have been cancelled.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 112 is respectfully requested.

III. The Rejections Under 35 U.S.C. § 102(b) Are Overcome

Claims 17-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Mulroy et al. (MPM-E21; 27th Annual Meeting, July 10-15, 1999). Applicants respectfully traverse this rejection.

The priority date for the limitation of intraocular pressure that is “greater than 100 mm Hg” recited in claims 17-20 is alleged to be that of the present application filed on February 12, 2001 and not that of the provisional parent application, U.S.S.N. 60/181,980, filed on February 11, 2000. The entire contents of Mulroy et al. are contained in the provisional parent application. See, for example, page 25 of U.S.S.N. 60/181,980, which contains a verbatim reproduction of the abstract. It is stated that the limitation of “greater than 100 mm Hg” is not disclosed in the provisional parent application. Yet, it is admitted by the Office that the methods of Mulroy et al. would have an intraocular pressure limit that is greater than 100 mm Hg. Therefore, the limitation of “greater than 100 mm Hg” is inherently disclosed in the provisional parent application.

To comply with the written description requirement of 35 U.S.C. § 112, first paragraph, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure. See M.P.E.P. § 2163. Given the admission by the Office that Mulroy et al. contains an inherent disclosure of the limitation in question, it therefore follows that page 25 of U.S.S.N. 60/181,980 also provides an inherent description of the very same limitation, i.e., of “greater than 100 mm Hg”. It is therefore respectfully submitted that the applicants are entitled to the priority date of February 11, 2000 for the limitation of intraocular pressure that is “greater than 100 mm Hg”. Accordingly, Mulroy et al. does not qualify as a prior art reference under 35 U.S.C. 102(b).

Reconsideration and withdrawal of the rejections of claims 17-20 under 35 U.S.C. § 102(b) is respectfully requested.

REQUEST FOR AN INTERVIEW

If any issue remains as an impediment to allowance, a further interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

In view of the amendments and remarks herewith, the application is in condition for allowance. Favorable reconsideration of the application, reconsideration, and withdrawal of the objections to and rejections of the application, and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

Respectfully submitted,

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